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April 16, 1999

Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Reference - Post Harvest Treatment of Molluscan Shellfish.

The Molluscan Shellfish has long been a product of the United States and other countries and has been harvested for consumption by the public for at least 150 years. The oyster is consumed in various manners, but has always been desired as a Raw Bar product and enjoyed by the public on the half shell, raw.

Recently it has come to my attention that there are efforts by a special interest group, the Center for Science in the Public Interest (CSPI) to encourage a mandatory post-harvest treatment or pasteurization of fresh oysters intended for raw consumption.. A regulation of this nature will impose new, costly and unnecessary regulations on the shellfish industry in general. More importantly, it will also take away the consumers choice between the regularly consumed fresh oyster and forcing the consumer to eat the treated product which totally changes the quality, taste and texture of the oyster.

Our firm W.H. Harris Seafood has been in the processing industry for 52 years. We offer the public a safe, delicious and natural Raw Bar product. As a participant in this industry, we have worked closely with the States, (ISSC) Interstate Shellfish Sanitation Conference, the (MSI) Molluscan Shellfish Institute, the (NFI) National Fisheries Institute and the (FDA) U.S. Food and Drug Administration in developing and initiating a campaign of consumer education and awareness about the "at risk" category which could be susceptible to illness from (V.v.) V. Vulnificus and (V.p.) Vibrio Parahaemeolyticus from shellfish. Results have been excellent and have greatly reduced serious illnesses and deaths by alerting those with pre-existing conditions of possible

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risk. Supporters of these proposed rules will admit that as few as only 15 to 20 people per year out of a total at risk population of 30 million are suspected at risk when consuming a raw oyster product. Currently there is insufficient data supporting a specific level and a link between V.v. levels and illness and death. The ISSC and most State Public Health bodies believe that consumer education is an intelligent, measured and appropriate response to health concerns and fully support continuing both the education campaigns and ISSC authority on the issue. We do not need a performance standard established for either V.v. or V.p. and we will oppose the establishment of a performance standard for Vibrio Bacteria.

We are also involved in a large seafood restaurant and the public desires and demands a raw oyster product. Sales of the raw oyster have been high. I believe that if this pasturized product is made mandatory, sales of the oyster will plummet. The pasturized product is of poor taste and poor quality and for a real oyster eater will not be considered as tasty.

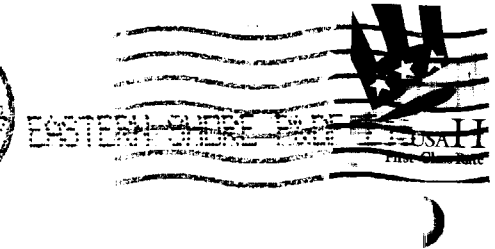
Consumer choice is an important part of our heritage here in America and I believe the consumer has the right to choose an oyster product that they have enjoyed for over 150 years raw-succulent and delicious. I urge the FDA to reject a mandatory post-harvest treatment requirement for all oysters. It is unnecessary and deprives the public of consumer choices.

Sincerely,

A handwritten signature in cursive script that reads "Karen Oertel". The signature is written in dark ink and is positioned above the printed name.

Karen Oertel
president

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